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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,742	03/25/2004	Clive Elson	4245/2092	9666

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,742	ELSON ET AL.	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *20-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed June 2, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claim 7 has been amended;
(B) Comments regarding Office Action have been provided drawn to:
  (I) restriction requirement, which has been maintained for the reasons of record;
  (II) disclosure objection, which is maintained for the reasons of record;
  (III) 2nd paragraph rejection, which is maintained for the reasons of record;
  (IV) 102(b) rejection, which is maintained for the reasons of record.

2. Claims 1-50 are pending in the case; Claims 20-50 are withdrawn from consideration.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4. Applicant's election with traverse of Group I, Claims 1-19, in the reply filed on June 2, 2006 is acknowledged. The traversal is on the ground(s) that searching and examining the other Groups along with Group I would not cause hardship. This is not found persuasive because of the reasons disclosed for restriction of the claims in paragraphs 2 and 3 of the Office Action filed December 2, 2005.

The requirement is still deemed proper and is therefore made FINAL.

5. Applicants are reminded that where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Objection to the Specification

6. The disclosure is objected to because of the following informalities: The formula " –C(C=O)-R-COG " which is set forth in the instant specification on page 2, lines 14, 16 and 17 is incorrectly written the first carbon atom in the formula does not contain the required number of bonds to complete the formula. This formula may have been intended to be written as " **–C(=O)**-R-COG " as set forth on page 4, line 23 of the instant specification. Also see this incorrectly written formula on page 4, lines 7, 9 and 10 (see the formula bridging lines 9 and 10).

Appropriate correction is required.

Response to Arguments

7. Applicant's arguments filed June 2, 2006 have been fully considered but they are not persuasive. Applicants argue that "although the formulas do not all show 4 bonds for the carbon atoms, it is standardcemical practice not to show the hydrogen atoms on the saturated carbons in the formula". This argument is not persuasive since the first paragraph of 35 U.S.C. 112 requires the specification to contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. Applicants further states that the formula " –C(C=O)-R-COG " clearly means " –CH(C=O)-R-CH_2OG ", which does not clear up the structure of the formula and further adds confusion to the description of the formula by presenting a totally different formula than what is disclosed in the specification. The formula disclosed in the remarks by Applicants which has the underlined group " –CH(C=O)-R-CH_2OG " is clearly not supported in the specification and the claims. Furthermore, even with the hydrogen atoms added to the structure, the underline group in the formula presented by Applicants in the remarks " –CH(C=O)-R-CH_2OG" is not correct since at least the underlined carbon atoms " –CH(C=O)-R-CH_2OG " or " –CH(C=O)-R-CH_2OG" (depending on the structure) still does not contain the required number of bonds attached to the carbon atoms to complete the formula. Accordingly, the objection to the specification because of improperly written formulas is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 2nd Paragraph

8. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, lines 8, 10 and 11, the formula " –C(C=O)-R-COG " is incorrectly written because the first carbon atom in the formula does not contain the required number of bonds to complete the formula. This formula may have been intended to be

written as " **–C(=O)**-R-COG ". See the correctly written formula on page 4, line 23 of the instant specification.

Claims 5 and 6 also set forth the incorrectly written formula " –C(C=O)-R-COG ", which should be corrected to read as " –C(=O)-R-COG ".

In Claim 10, the metes and bounds of the subject matter thereof cannot be determined since the claims and specification do not disclose what heteroatoms can included in the R group. One would have to guess as to what heteroatoms Claim 10 is referring to.

Claim 11 being drawn to a single polymer compound lacks proper antecedent basis by using the phrase "and mixtures thereof". This phrase suggests that a composition comprising 2 or more components is being claimed, which does not appear to be the case in the currently written claims.

Claim 19, lines 1 and 2, the phrase "said therapeutic agent" lacks clear antecedent basis by being dependent from Claim 13 since "therapeutic agent" was not previously recited in Claim 13 or in claims from which Claim 13 is dependent from.

Claims 2-4 and 7-19 are also rejected since these claims are dependent from the rejected claims and do not clarify errors set forth therein.

Response to Arguments

9. Applicant's arguments filed June 2, 2006 have been fully considered but they are not persuasive. Applicants argue that Claim 1 is a classic Markush group whereby any of these polymer, or a mixture of two or more, can be used as the polymer in claim 1. This argument is not persuasive since Claim 1 is drawn to a polymer (one compound) wherein the Markush terminology sets forth alternative structures of the polymer. The phrase "mixtures thereof" in Claim 11 indicates a combination of two or more of the "alternative structures of the polymer" being present together to form a mixture, which is improper or lack clear antecedent basis by Claim 11 being dependent from Claim 1 since Claim 1 is only drawn to one polymer (which has alternative structures).

See the above argument under "objection to the specification" regarding the improper formulas disclosed in the claims.

Accordingly, the rejection of the claims under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

10. Claims 1-8 and 11-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Elson (US Patent No. 5,888,988) for the reasons disclosed on pages 6-8 of the Office Action filed December 2, 2005.

Response to Arguments

11. Applicant's arguments filed June 2, 2006 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the succinylated N,O-carboxymethyl chitosan (NOCC) disclosed in the Elson patent binds to an amino group of a second NOCC chain and argues that this compound is entirely a different molecule that the N,O-carboxymethyl N-succinylchitosanchitosan claimed in claim 11 and encompassed by claim 1 of the present application. This argument is not persuasive because the Elson patent does set forth a succinylated NOCC compound before the succinic carboxylate moieties are directly linked to amino groups of a second NOCC chain (see column 7, last line to column 8, line 5). Accordingly, the rejection of Claims 1-8 and 11-19 under 35 U.S.C. 102(b) as being anticipated by the Elson patent is maintained for the reasons of record.

Reply to Final Must Include Cancellation of Claims Non-Elected with Traverse

12. This application contains Claims 20-50 drawn to an invention nonelected with traverse in the Paper filed June 2, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Summary

13. Claims 1-19 are rejected; Claims 20-50 are withdrawn from consideration.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. White

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8/10/06

Shaojia A. Jiang
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